DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

9/810d

CERTIFIED MAIL
RETURN RECEIPT REQUEST

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (714) 798-7600

WARNING LETTER

October 2, 2001

WL-02-02

T. R. Phillips
President
Pacific Precision, Inc.
425 Borrego Court
San Dimas, CA 91773

Dear Mr. Phillips:

During an inspection of your firm located in San Dimas, California, from August 20 to 23, 2001, our investigator determined that your firm manufactures dental endosseous implants, abutments and accessories. These dental products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection disclosed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, and storage are not in conformance with the Good Manufacturing Practice (GMP) requirements for the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to appoint, and document such appointment of, a member of management who irrespective of other responsibilities shall have established authority over and responsibility for ensuring that quality system requirements are effectively maintained and to report on the performance of the quality system to management with executive responsibility [21 CFR 820.20(b)(3)].

2. Failure to establish and implement procedures for conducting management reviews; no management reviews have been conducted at defined intervals to ensure the quality system satisfies the requirements of the Quality Systems Regulation and established quality policy and objectives [21 CFR 820.20(c)].

3. Failure to establish and implement procedures for conducting quality audits; no audits have been conducted to verify that the quality system is effective in fulfilling the quality system objectives [21 CFR 820.22].

4. Failure to establish procedures for implementing corrective and preventive action addressing the analysis of sources of quality data to identify existing and potential causes of nonconforming product or other quality problems [21 CFR 820.100(a)].

5. Failure to ensure that the acceptance procedures for the acceptance or rejection of finished device production lots are complete [21 CFR 820.80(d)]. Specifically, the sampling plan(s) and acceptance criteria for final release are not defined.

6. Failure to control procedures for ensuring that the Device History Records for each production lot are properly maintained to demonstrate that the devices are manufactured in accordance with the Device Master Record [21 CFR 820.184]. Specifically, device history records do not describe the machining and deburring operations, the CNC lathes program used, the individual(s) who performed the operation(s), the quantity of devices manufactured, the dates of manufacture, and the sampling plan used for inspecting and the equipment used in the tests.

7. Failure to ensure that all inspection, measuring and test equipment is suitable for its intended purposes and is capable of producing valid results [21 CFR 820.72]. Specifically, there was no documentation describing any calibration activities performed to the Gage optical comparator used for final inspection of the devices.

Additionally, our records show that you have not registered your facility or listed your devices, as the law requires. The failure to register and list causes your devicess to be misbranded under section 502(o) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Exportability will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

If you have any questions relating to this letter please contact Senior Compliance Officer, Dannie E. Rowland at (949) 798-7649.

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

Sincerely,

Alonza E. Cruse
District Director
Los Angeles District Office

Cc: State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Branch
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Sacramento, CA 94234-7320